

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 02-865V

Filed: March 16, 2010

Not For Publication

MALKAH PESSEL BERGER and ARYEH
BERGER, on their own behalf and as best
friends of their daughter, Chana Rochel
Berger,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES,

Respondent.

DECISION ON THE
RECORD; TABLE CLAIM;
CAUSATION IN FACT
CLAIM; DTaP VACCINE;
CEREBRAL PALSY;
OMNIBUS AUTISM
PROCEEDING

John F. McHugh, Esq., New York, NY, for petitioners.

Linda S. Renzi, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

Vowell, Special Master:

On July 19, 2002, Malkah and Aryeh Berger ["petitioners"] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² [the "Vaccine Act" or "Program"], on behalf of their minor daughter,

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

Chana Berger ["Chana"], alleging that Chana experienced reactions to vaccines³ she received on August 2, 1999, and was later diagnosed with cerebral palsy. Pet. ¶¶ 4, 5, 15. They asserted that this reaction constituted a Vaccine Table injury,⁴ but did not file any medical expert opinion stating that Chana's condition constituted such an injury.⁵

I. Procedural History.

The medical expert's report was filed on December 4, 2002. During a status conference on February 20, 2003, the special master noted discrepancies between the medical records and affidavits filed by Malkah Berger and several other relatives. See Order, filed Feb. 21, 2003. Petitioners filed additional information, including a declaration from Chana's pediatrician. To resolve discrepancies that still existed, the special master set the case for a hearing on July 28, 2003, to establish the facts and circumstances surrounding Chana's injury. Order, filed June 20, 2003.

After the hearing concluded and the transcript was filed, another telephonic status conference ensued. Although the order memorializing this status conference does not specifically reflect what transpired, the order directed petitioners to file a status report indicating when they could file the report of an expert supporting a causation in fact claim. Order, filed Aug. 26, 2003. This order suggested that the special master had concluded that petitioners had failed to establish a factual basis for the Table injury claim, a conclusion buttressed by both a petitioners' status report on November 4, 2003,⁶ and a subsequent order by the special master, filed on January 29, 2004, which is discussed below.

On December 5, 2003, petitioners filed a status report reiterating that the special master had determined that the petitioners had failed to establish a Table injury. Rather than proposing a schedule for filing an expert report regarding an actual

³ These vaccines were identified in the petition as "ADTP," "IPV" and "HIB". Petition ["Pet."] ¶ 4. Other evidence indicated that Chana received a diphtheria, tetanus, and acellular pertussis ["DTaP"] vaccination on that date, along with inactivated polio ["IPV"] and haemophilus influenzae type b ["Hib"] vaccinations. Petitioners' Exhibit ["Pet. Ex.] E, pp. 29 (vaccination record), 30 (examination record).

⁴ A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3 (2009), corresponding to the vaccine received within the time frame specified. Because the Table injury petitioners claimed was an encephalopathy (as discussed *infra*), and the pertussis vaccine is the only vaccine Chana received on the date specified for which encephalopathy is listed as a Table injury, the Table claim concerned the pertussis vaccine.

⁵ On four separate occasions, the assigned special master ordered petitioners to correct this defect by filing a "medical expert's opinion that supports a *prima facie* Vaccine Injury Table . . . claim." Order, filed Aug. 23, 2002; see also Orders, filed Oct. 8, 2002; Oct. 23, 2002; Nov. 27, 2002.

⁶ The November 4, 2003 petitioners' status report states: "The Court has informed the parties that it had determined that the petitioners did not establish a table injury."

causation claim, the petitioners “respectfuylly [sic] request[ed] that this action be merged withg [sic] the Omnebus [sic] Autism matter for a determination whether a neurological injury can result from the DPaT [sic] and other vaccinations Chana Berger received.” The special master filed an order addressing this request on January 29, 2004, which indicated that petitioners were pursuing both a Table injury claim and an actual causation claim. Order, filed Jan. 29, 2004. The order also indicated that petitioners “acknowledge that Chana’s medical records that are contemporaneous with Chana’s August 2, 1999 DTap vaccination do not confirm their current recollections about Chana’s condition during the 72-hour period following the . . . vaccination.” *Id.* at 1-2. The special master then summarized the August 25, 2003 status conference and petitioners’ response thereto by stating:

On August 25, 2003, the special master convened an informal, yet substantive, status conference. He discussed frankly and comprehensively his assessment of the lay testimony. He concluded that the lay testimony was not persuasive. Thus he determined that the Bergers had not established a factual basis for a presumptive causation claim. He recognized that a formal written decision incorporating his informal comments had the potential to cause the Bergers undue emotional distress. Therefore, he offered the Burgers the option to waive a formal written decision on credibility issues, ending effectively proceedings on their presumptive causation claim. The Bergers accept apparently the special master’s informal decision on credibility issues. See Status Report, filed December 5, 2003, at 1. As a consequence, they desire to opt into the Autism Omnibus Proceeding.

Order, filed Jan. 29, 2004, at 2. Although no formal waiver of a written decision was ever filed, the special master apparently treated the OAP reassignment request as one. The case was reassigned on January 29, 2004 to the special master then presiding over the Omnibus Autism Proceeding [“OAP”].

What was lacking in this reassignment was any evidence that Chana had autism or any similar neurological condition. Autism General Order #1,⁷ the order of the Chief Special Master that established the OAP, permitted pending cases alleging that vaccines had caused autism or an autism spectrum disorder⁸ to be transferred into the

⁷ See Autism General Order #1, filed July 3, 2002, Ex. A, *available at* <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf> [“Autism Gen. Order #1”], 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002). It established the OAP to address issues arising from the unprecedented filing of more than 300 petitions for compensation in a six-month period, all alleging that vaccines caused a neurodevelopmental disorder known as autism or an ASD.

⁸ The order defined an autism spectrum disorder as:

[A] brain disorder affecting a person’s ability to communicate, form relationships, and/or

OAP:

Any petitioner with a *pending autism-related claim*, who has not yet requested to have proceedings in his own case stayed for the duration of the Omnibus Autism Proceeding, may do so simply by filing a Notice to Stay Proceedings Once that is done, no case-specific proceedings will be held in that case until further notice, and that case will be treated as described in the previous paragraph.

Autism Gen. Order #1 at 7 (bold added, italics in original).

Nevertheless, petitioners' case was stayed, pending resolution of the general causation issues in the OAP. Notice Regarding "Omnibus Autism Proceeding," filed Feb. 11, 2004. The case was reassigned to me on February 26, 2007, after two additional special masters were assigned to the OAP docket, and the nearly 5,000 pending OAP cases were divided among the three special masters so assigned.⁹

Petitioners' case remained stayed until January 15, 2008, when, in accordance with procedures established to begin moving OAP cases towards resolution, a "Phase 1" order was issued.¹⁰ Petitioners responded with a status report on January 31, 2008, addressing the timely filing of the claim. Thereafter, respondent filed a statement agreeing that petitioners' claim was timely filed, but asserting that the case should not be a part of the OAP because Chana had cerebral palsy, not autism. See Respondent's Statement Regarding Jurisdiction and Appropriateness of Proceeding Within The Court's Omnibus Autism Proceeding, filed Mar. 17, 2008, at 2. On April 4,

respond appropriately to the environment. Such disorders sometimes result in death. The "spectrum" of such disorders includes relatively high-functioning persons with speech and language intact, as well as persons who are mentally retarded, mute, or with serious language delays. Symptoms may include, but are not limited to, avoidance of eye contact, seeming "deafness," abrupt loss of language, unawareness of environment, physical abusiveness, inaccessibility, fixation, bizarre behavior, "flapping," repetitive and/or obsessive behavior, insensitivity to pain, social withdrawal, and extreme sensitivity to sounds, textures, tastes, smells, and light.

Autism Gen. Order #1 at n.2 (internal citation omitted).

⁹ On January 11, 2007, Chief Special Master Golkiewicz assigned two additional special masters to the OAP docket. Special Master Campbell-Smith and I were the two additional special masters assigned. See Notice Regarding Assignment of Autism Cases to Additional Special Masters, OAP Master File, filed Jan. 11, 2007 (setting forth the reasons for detailing two additional special masters). The publicly accessible website, www.uscfc.uscourts.gov/omnibus-autism-proceeding, contains the OAP Master File (under the "docket" link), which includes orders, decisions, and periodic updates issued by the special masters assigned to the docket.

¹⁰ A "Phase 1" order required the filing of sufficient medical records to determine if the vaccinee had a diagnosis on the autism spectrum and whether the claim was timely filed.

2008, I ordered petitioners to respond to respondent's assertion. No response was received.

I reiterated the order on September 29, 2009. This time petitioners' counsel responded, indicating that he was attempting to locate his clients, and requesting additional time. Petitioner's Reply to the Order, filed Oct. 26, 2009. On October 30, 2009, a supplemental reply acknowledged that Chana did not have an autism diagnosis, and thus the case should not be a part of the OAP.

On November 5, 2009, I ordered the case "decoupled" from the OAP. I conducted a status conference on November 18, 2009 to determine how to proceed. Order, dated Nov. 19, 2009. On January 4 and 7, 2010, petitioners' counsel filed status reports indicating that petitioners had contacted his office and no longer wished to proceed with their case. Petitioners' counsel "confirmed this instruction by letter asking the family to inform this office immediately if this instruction or our understanding of it were incorrect. We have not had a reply. Therefore, we suggest that the Court enter judgment based on the decision in the record." Status Report, filed Jan. 7, 2010. No further filings by either party have been received, and it appears that this case is as ripe for resolution as it is likely to be.

II. The Merits of the Causation Claims.

The Vaccine Act has two separate methods by which a petitioner may establish entitlement to compensation for an injury. A petitioner may show by a preponderance of the evidence either that: (1) the vaccine recipient sustained a Table injury or (2) the vaccine recipient's injury was actually caused by a vaccine. § 300aa-11(c)(1)(C).

The posture of this case is more complicated than that of most cases in which a petitioner requests a ruling on the record because no definitive written ruling on the original Table claim was ever issued by the special master originally assigned. Although petitioners apparently acquiesced to the special master's informal determination that the medical records surrounding Chana's injury were more persuasive than the conflicting oral testimony, the Table injury claim was never formally withdrawn. Therefore, in ruling on this record, I must rule on both the Table claim and the causation in fact claim.

A. The Table Injury Claim.

I have reviewed the medical records, the report of petitioners' expert,¹¹ the

¹¹ Doctor Spitz opined that Chana's August 2, 1999 vaccinations produced an immediate acute encephalopathy. Opinion of Dr. Spitz, filed Dec. 4, 2002 (this report was never assigned an exhibit number). The report focused only on the Table injury claim and thus did not address the issue of how any of the vaccines received could actually cause Chana's cerebral palsy.

“declarations” filed by Chana’s family, the statement of the physician who administered the vaccination, and the complete transcript of the hearing convened to determine the facts surrounding Chana’s vaccination and subsequent condition.¹² I come to the same conclusion as did the previous special master: the contemporaneous medical records are more probative than the other evidence filed.¹³

The Qualifications and Aids to Interpretation [“QAI”] portion of the Table¹⁴ adds, in essence, definitions for the terms used in the Table. One of the conditions specified for compensation after receipt of a pertussis-containing vaccine is an encephalopathy within 0-72 hours from administration of the vaccine. Chana’s condition in the 72 hours following her vaccination did not fit the Table definition of an encephalopathy, Dr. Spitz’s opinion notwithstanding.

The QAI provides in pertinent part:

(2) Encephalopathy. For purposes of the [Vaccine Injury Table], a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) For children less than 18 months of age who present

¹² In view of the role the credibility of witnesses may have played in Special Master Edwards’ determination that petitioners had failed to establish the factual predicates for a Table injury claim, I afforded petitioners the opportunity to request another fact hearing if they wished to pursue a Table injury claim. See Order, filed Nov. 19, 2009, at 2 (If petitioners decide they wish to pursue the Table claim, “they shall inform me at the [next] status conference as to whether they want (i) a ruling regarding onset based on the existing factual record, which includes the transcript of the July 28, 2003 hearing; or (ii) another fact hearing.”); see also Order, filed Dec. 15, 2009. Petitioners did not make any election, indicating instead that they no longer desired to pursue their claim.

¹³ Special masters frequently accord more weight to contemporaneously recorded medical symptoms than those recounted in later medical histories, affidavits, or trial testimony. “It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.” *Murphy v. Sec’y, HHS*, 23 Cl. Ct. 726, 733 (1991). See also *Cucuras v. Sec’y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Memories are generally better the closer in time to the occurrence reported and when the motivation for accurate explication of symptoms is more immediate. *Reusser v. Sec’y, HHS*, 28 Fed. Cl. 516, 523 (1993). Inconsistencies between testimony and contemporaneous records may be overcome by “clear, cogent, and consistent testimony” explaining the discrepancies. *Stevens v. Sec’y, HHS*, No. 90-221V, 1990 WL 608693, at *3 (Fed. Cl. Spec. Mstr., Dec. 21, 1990).

¹⁴ The Vaccine Injury Table must be interpreted by reference to the QAI’s definition of key terms. *Althen v. Sec’y, HHS*, 58 Fed. Cl. 270, 280 (2003), *aff’d*, 418 F.3d 1274 (Fed. Cir. 2005).

without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. . . .

(D) A “significantly decreased level of consciousness” is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater . . . :

- (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
- (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
- (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

42 C.F.R. § 100.3(b) (2009). Considered as a whole,¹⁵ the evidence does not establish that Chana had a significantly decreased level of consciousness lasting at least 24 hours after her vaccination.

Because I have so concluded, I accord Dr. Spitz’s report and testimony that Chana suffered an encephalopathy no weight. As the Court of Federal Claims has noted, a doctor’s “conclusions . . . are only as good as the reasons and evidence that support them.” *Davis v. Sec’y, HHS*, 20 Cl. Ct. 168, 173 (1990). The supporting evidence for Dr. Spitz’s opinions was not adequately established. Therefore, I conclude that petitioners have not presented a *prima facie* case for a Table injury.

B. Cause in Fact Claim.

To establish legal cause in an “off-Table” case, Vaccine Act petitioners must establish each of the three *Althen* factors: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. 418 F.3d 1274, 1278 (Fed. Cir. 2005). The applicable level of proof is the “traditional tort standard of ‘preponderant evidence.’” *Moberly v. Sec’y, HHS*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (citing *de Bazan v. Sec’y, HHS*, 539 F.3d 1347, 1351 (Fed. Cir. 2008); *Pafford v. Sec’y, HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Capizzano v. Sec’y, HHS*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *Althen*, 418 F.3d at 1278). The preponderance standard “requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence.” *In re Winship*, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring) (internal quotation and citation omitted).

¹⁵ See § 300aa–13(a): “Compensation shall be awarded...if the special master or court finds on the record as a whole....” See also § 300aa–13(b)(1) (indicating that the court or special master shall consider the entire record in determining if petitioner is entitled to compensation).

At the November 18, 2009 status conference, petitioners' counsel agreed to initiate a medical expert's review of this case in support of petitioners' causation in fact claim. Accordingly, petitioners were ordered to file their expert report by no later than Tuesday, February 16, 2010. Order, filed Dec. 15, 2009. No report of a medical expert causally linking Chana's vaccination to her cerebral palsy has been filed, and the record does not contain any reliable evidence indicating that Chana's vaccine was responsible for her injury. Thus, petitioners have failed to establish a *prima facie* case for causation in fact.

III. Conclusion.

Petitioners have not demonstrated by a preponderance of the evidence that Chana's condition was either a Table injury or caused in fact by her vaccination. Thus, they have failed to establish entitlement to compensation and the petition for compensation is therefore **DENIED**. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.¹⁶

IT IS SO ORDERED.

Denise K. Vowell
Special Master

¹⁶ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.